

K 123168

Section 7: 510(k) Summary

DEC 20 2012

Introduction:

This document contains the 510(k) Summary for the Q-Plus T +IPL laser system. The content of this summary is based on the requirements of 21 CFR 807.92(c).

**Applicant / Manufacturer
Name and Address:**

Quanta System SPA
Via IV Novembre, 116
Solbiate Olona (VA)
Italy, 21058

510(k) Contact Person:

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Date Prepared:

October 5, 2012

Device Name:

Q-Plus T + IPL Laser System

Classification:

Class II

Classification Name:

Laser surgical instrument for use in general
and plastic surgery and in dermatology

Regulation Number

21 CFR 878.4810

Product Code:

GEX

Predicate Devices:

The Q-Plus T + IPL Laser System is claimed to be substantially equivalent to the following legally marketed predicate devices:

- K073549 Q-Plus T manufactured by Quanta System SPA
- K083207 Ultrawave III EX 1320 manufactured by Quanta System SPA

Performance Standards:

There are no mandatory performance standards for this device.

General Device Description:

The Q-Plus T + IPL Laser System is intended for the incision, excision, ablation and vaporization of soft tissue for general dermatology. The device includes a Q-Switched Nd:YAG laser source with a max energy of 1000mJ at 1064nm and a max energy of 500mJ at 532nm, a Q-Switched Ruby laser source with a max energy of 1000mJ at 694nm, and an intense pulse light (IPL) hand piece. The Q-Switched lasers are intended for treatment of pigmented lesions and tattoo removal. The optical delivery system for the three laser wavelengths is an articulated arm with replaceable hand pieces with 2, 3, 4, and 6 mm spot sizes. The IPL hand piece, depending on the particular wavelength filter used, is intended for hair removal, treatment of dermatological vascular lesions, benign pigmented lesions and inflammatory acne (acne vulgaris). The IPL hand pieces are provided in a fixed or a replaceable configuration.

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The Q-Plus T + IPL laser system incorporates several safety features, including a remote interlock, a key switch and an emergency stop button.

Indications for Use:

Source selection and wavelength	Indications for Use
Nd:YAG laser (1064nm) Nd:YAG laser (532nm)	These wavelengths are absorbed by natural chromophores, like melanin, hemoglobin and water and by exogen pigments like tattoo ink. They are indicated for: Tattoo removal: 1064nm: suggested for dark blue and black ink 532nm: suggested for red, orange, yellow, and purple ink Pigmented lesion removal (benign): Café au lait spot Ephalides, solar lentigo (lentigines) Becker Nevus Ota Nevus Nevus spilus
Ruby laser (694nm)	This wavelength is absorbed by natural chromophores, like melanin, hemoglobin and water and by exogen pigments like tattoo ink. It is indicated for: Tattoo removal: Suggested for blue, sky blue, black, green and violet ink Pigmented lesion removal (benign): Café au lait spot Ephalides, solar lentigo (lentigines) Becker Nevus Ota and Ito Nevus Nevus spilus Mongolian spot
IPL 650-1200nm IPL 625-1200nm IPL 590-1200nm	Indicated for hair removal
IPL 550-1200nm IPL 570-1200nm	Indicated for photocoagulation of dermatological vascular lesion (i.e. face telangiectasia), photothermolysis of blood vessels (treatment of facial and leg veins), and treatment of benign pigmented lesions
IPL 550-1200nm	Indicated for face vascular lesions and solar lentigines (benign pigmented lesions)
IPL 400-1200nm	Indicated for inflammatory acne (acne vulgaris)

Comparison of Technological Characteristics:

The Q-Plus T + IPL Laser System has substantially equivalent technological characteristics to the predicate devices. The ten subsystems in the Q-Plus T + IPL laser system contain all nine subsystems of the Q-Plus T (K073549) with the addition of the IPL hand piece subsystem that is cleared with the Ultrawave III EX 1320 (K083207).

The Q-Switched Nd:YAG laser source with a max energy of 1000mJ at 1064nm and a max energy of 500mJ at 532nm is identical to the Q-Switched Nd:YAG laser source utilized in the Q-Plus T device. Also, the Q-Switched Ruby laser source with a max energy of 1000mJ at 694nm is identical the Q-Switched Ruby laser source utilized in the Q-Plus T device. The optical delivery system for the three laser wavelengths is an articulated arm that is also used in the Q-Plus T device. The IPL hand piece portion of the Q-Plus T + IPL Laser System is the same as the IPL hand piece portion of the Ultrawave III EX 1320. In addition, the Q-Plus T + IPL laser system includes a power supply, a cooling system, an optical delivery system, a microprocessor based

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controller, and safety features that are all either similar or identical to those in the Ultrawave III EX 1320 and Q-Plus T devices.

The laser specifications for the Q-Plus T + IPL laser system are substantially equivalent to the laser specifications for its identified predicate device with respect to the laser source, wavelengths, maximum energy, spot size, fluence, pulse width, repetition rate, beam delivery, power monitor, actuator, and aiming beam.

Comparison of Intended Use:

The Q-Plus T + IPL laser system is a laser surgical instrument for use in general surgery and dermatology intended for the incision, excision, ablation, and vaporization of soft tissue and for the treatment of vascular and pigmented lesions, tattoo removal, hair removal, and inflammatory acne (acne vulgaris).

The intended use of the laser portion of the Q-Plus T + IPL laser system is the same as the intended use of the previously cleared Q-Plus T as no changes have been made with regard to performance or technology to the Q-Plus T. Furthermore, no changes have been made to the IPL hand piece portion of the subject device since its initial clearance in K051113 and its clearance for use with the Ultrawave III EX 1320 in K083207. Therefore, the intended use of the IPL hand piece used with the Q-Plus T + IPL laser system is substantially equivalent to the intended use of the IPL hand piece used with the Ultrawave III EX 1320.

Substantial Equivalence:

The Quanta System Q-Plus T + IPL laser system is as safe and effective as the predicate devices. The Q-Plus T + IPL laser system has the same intended use and similar technological characteristics and principles of operation as its predicate devices. The minor technological differences between the Q-Plus T + IPL laser system and its predicate devices raise no new issues of substantial equivalence or safety and effectiveness. Thus, the Q-Plus T + IPL laser system is substantially equivalent to its identified predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Quanta System Spa
% Mr. Maurizio Bianchi
Regulatory Affairs Manager
Via IV Novembre, 116
Solbiate Olona, VA
Italy 21058

Letter dated: December 20, 2012

Re: K123168

Trade/Device Name: Q-Plus T + IPL Laser System

Regulation Number: 21 CFR 878.4810

Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology

Regulatory Class: II

Product Code: GEX

Dated: October 05, 2012

Received: October 09, 2012

Dear Mr. Bianchi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA).

You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123168

Device Name: O-Plus T + IPL Laser System

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IPL 400-1200nm	Indicated for inflammatory acne (acne vulgaris)

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-the Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Neil R Ogden
2012.12.19 11:23:24 -05'00'

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical Devices
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